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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,051	04/26/2001	Martin T. Gerber	P008433.00CIP1	8909

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EXAMINER
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EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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07/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/843,051

Applicant(s)

GERBER ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-38 and 40-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-38, 40-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-26, 29-31, 33, 34, 36-38, 40-43, 46, and 47 are rejected under 35

U.S.C. 102(b) as being anticipated by Hoffmann et al (5534022). Hoffmann shows in figure 13 the use of a distal ring electrode, 38, coil electrode, 20, proximal ring electrode, 36, and another proximal ring electrode as element 20'. Hoffmann also shows the use of electrode connector, e.g. 27/26/29, in figures 4, 5, or 7 and incorporates by reference 08/018832 (patent 5385578) to describe how the electrode is welded/adhered/connected to the conductor. In addition, Hoffman is capable of meeting the functional use recitations presented in the claims of being used for insertion through the sacrum into position for stimulation of one or more sacral nerves without causing damage since Hoffmann's lead is of a similar size (about 2.5 mm) and shape as the applicants lead and Hoffmann's lead is very flexible and used in the veins and the heart (e.g. figures 9, 10, column 3, etc.). Finally, Hoffmann's coil electrode, 20, includes a wire coil since it is a "coil" electrode that is made of wire coils (e.g. col. 6).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28, 32, 35, and 45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffmann.

Hoffman discloses the claimed invention having a diameter of "about 2.5 mm" which meets the limitation of the applicants claim language of "about 2 mm" and shows in figures 4, 5, 7 and 8 and describes in the incorporated reference, 08/018832, how the electrode is welded to the electrode connector as a butt weld.

In the alternative, Hoffmann discloses the claim invention except for the diameter of the coil being about 0.5 to about 2 mm and the connector being butt-welded to the electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Hoffmann, with the diameter of the coil being about 0.5 to about 2 mm and the connector being butt-welded to the electrode since it was known in the art that implantable leads use: the diameter of the coil being about 0.5 to about 2 mm to provide an implantable lead that is small, unobtrusive, and does not interfere with the bodies

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functions; and the connector being butt-welded to the electrode to provide a secure, reliable, and easily produced connection to connect two elements.

In addition, for the claimed 0.5-2 mm range, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05

Claims 27 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann.

Hoffman discloses the claimed invention except for the length of the coil electrode to be 0.1 to 1.5 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Hoffmann, with the length of the coil electrode to be 0.1 to 1.5 inches since it was known in the art that coil electrodes are provided in the length of 0.1 to 1.5 inches to allow the coil electrode to be placed near the area that needs stimulation without needing the precise placement of say a point electrode and/or to provide the appropriate stimulation field to effectively stimulate a particular area of the body.

### ***Response to Arguments***

Applicant's arguments filed 4/2/07 have been fully considered but they are not persuasive. The argument that the defibrillation electrode of Hoffman is not analogous to the coil stimulation electrode recited in claim 22 is not persuasive since the claim only states that the

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coil electrode includes a wire coil and an electrode connector, which Hoffman contains as described above in the rejection. In addition, it is unclear why the applicant is focusing on the sensing feature of Hoffman's defibrillation electrode since a "defibrillation" electrode is meant to deliver stimulation to the body. It is noted that the parameters of the stimulation have not been set forth, that electrodes are meant to deliver a range of stimulation energies, from pacing to defibrillation, and that the claim is an open ended "comprising" claim and does not preclude the use of the electrode for sensing. The argument that Hoffman's electrode is not capable of meeting the functional use recitations presented in the claim(s) is not persuasive. As set forth in the above rejections, Hoffman's range of "about 2.5 mm" is similar to applicant's size of "about 2.0 mm" and Hoffman's lead is flexible (e.g. col. 3, claim 19 of Hoffman, etc) and similar in shape. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The argument that Hoffman's electrode 20' is not a ring electrode is not persuasive since Hoffman's electrode is circular shaped (i.e. a ring), a ring is defined as one spiral of a helix/spiral (such as Hoffman's), the art recognized definition of a ring electrode also includes coil electrodes, and/or Hoffman's electrode is not just comprised of the wire coils, but also the conductive ring shaped element 28. The argument that the modifications suggested in the 103 rejections would render the lead of Hoffman unsuitable for its intended purposes is not persuasive because the applicant has not provided any reasoning why it would render the lead unsuitable for its intended purposes, since using smaller leads, such as about 2.0

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mm, and an electrode length of 0.1-1.5 inches is well known in the art (as shown by the evidence previously provided), and since these modifications do not render the lead unsuitable.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
George R Evanisko  
Primary Examiner  
Art Unit 3762

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GRE  
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